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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,708	10/15/2003	Hideya Takeo	Q77911	3651
23373	7590	01/03/2007	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			MOTSINGER, SEAN T	
			ART UNIT	PAPER NUMBER
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SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	01/03/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/684,708	TAKEO ET AL.
	Examiner Sean Motsinger	Art Unit 2635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10/15/2003.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 21 and 22 is/are allowed.  
 6) Claim(s) 1-20 and 20-24 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 15 October 2003 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date: _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/15/2003, 3/16/2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

***Objections to the Drawings***

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the distribution image of claim 21-23 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application.

***Objections to the Specification***

2. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: "The pattern, which is detected by the abnormal pattern candidate detection processing systems, is the candidate for the abnormal pattern, and a person, such as a medical doctor..." (see lines 7-10 on page 5.)

***Rejections Under 35 U.S.C. 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 7-12, 17-20, 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims contain means plus function limitations invoking 112 6<sup>th</sup> paragraph but no corresponding structure is found in the specification. The MPEP section.2181 states: 35 U.S.C. 112, sixth paragraph states that a Claim limitation expressed in means-plus-function language "shall be construed to cover the corresponding structure...described in the specification and equivalents thereof." "If one employs means plus function language in a Claim, one must set forth in the specification an adequate disclosure showing what is meant by that language. If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly Claim the invention as required by the second paragraph of section 112." In re Donaldson Co., 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc). For the purpose of advancing prosecution, the Claims are treated below on the interpretation that applicant intends any reasonable means for accomplishing such function.

### ***Rejections Under 35 U.S.C. 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 1, 4-7, 10-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Nishikawa US 6,058,332.
5. Re Claim 1 Nishikawa discloses, an abnormal pattern candidate detection processing method, comprising the steps of: i) detecting an abnormal pattern candidate, which is embedded in a medical image, in accordance with a medical image signal representing a medical image, (see abstract) and ii) outputting at least information for specifying the detected abnormal pattern candidate (see abstract), wherein the method further comprises the step of calculating a degree of certainty about malignancy (i.e. likelihood of malignancy), which degree represents a level of possibility of a pattern being a malignant pattern, with respect to the abnormal pattern candidate (see column 33 lines 13-25), the calculation being made in accordance with an index value representing a feature of the abnormal pattern candidate and in accordance with a correlation between the index (i.e. ANN output) value and possibility of a pattern being a malignant pattern (see column 33 lines 13-25), which correlation has been obtained from clinical results (see column 33 lines 13-25.) Note the correlation depends on the probability distribution of malignant and benign cases. The step of outputting at least the information for specifying the detected abnormal pattern candidate is a step of outputting information representing the degree of certainty about malignancy with respect to the abnormal pattern

candidate together with the information for specifying the detected abnormal pattern candidate (see column 36 lines 50-57.)

6. Re claim 4 Nishikawa further discloses wherein the information representing the degree of certainty about malignancy (i.e. likelihood of malignancy) is a numerical value (see column 33 lines 13-25 column 36 lines 50-55.) Note that likelihood of malignancy is disclosed as a numerical value.
7. Re claim 5 Nishikawa further discloses wherein the information representing the degree of certainty about malignancy is a warning message, which is altered in accordance with the degree of certainty about malignancy (see column 33 lines 13-25 column 36 lines 50-55.) Note that likelihood of malignancy is disclosed as a numerical value, which is altered, based on the degree of likelihood of malignancy and thus constitutes a warning message.
8. Re claim 6 Nishikawa further discloses wherein the medical image is a mammogram (see abstract.)
9. Re claim 7 Nishikawa discloses, An abnormal pattern candidate detection processing system, comprising: i) abnormal pattern candidate detecting means for detecting an abnormal pattern candidate, which is embedded in a medical image, in accordance with a medical image signal representing a medical image (see

abstract), and ii) image output means for outputting at least information for specifying the detected abnormal pattern candidate (see abstract), wherein the system further comprises malignancy certainty degree calculating means for calculating a degree of certainty about malignancy (i.e. likelihood of malignancy), which degree represents a level of possibility of a pattern being a malignant pattern, with respect to the abnormal pattern candidate (see column 33 lines 13-25), the calculation being made in accordance with an index (i.e. ANN output) value representing a feature of the abnormal pattern candidate and in accordance with a correlation between the index value and possibility of a pattern being a malignant pattern (see column 33 lines 13-25.) The correlation has been obtained from clinical results (see column 33 lines 13-25.) Note that the correlation depends on the probability distribution of malignant and benign cases. The image output means outputs information representing the degree of certainty about malignancy with respect to the abnormal pattern candidate together with the information for specifying the detected abnormal pattern candidate (see column 36, lines 50-57.) Note that in column 8, lines 9-34, and figure 2 Nishikawa discloses a computer system "means" configured to perform the above method.

10. Re Claim 10-12, Claims 10-12 are rejected for the same reasons as Claims 4-6.

Despite one set of claims being a method and one being a system the additional limitations added by these claims are the same. Therefore the prior art applied which teaches the method also teaches the corresponding systems.

11. Re Claim 13, Nishikawa discloses, An abnormal pattern candidate detection processing method, comprising the steps of: i) detecting an abnormal pattern candidate, which is embedded in a medical image, in accordance with a medical image signal representing a medical image(see abstract), and ii) outputting at least information for specifying the detected abnormal pattern candidate (see abstract), wherein the method further comprises the step of selecting an arbitrary region in the medical image ( see column 18 lines 25-35 and column 36 lines60-65.) Note that the system defines regions which define clusters which are described as arbitrary. Calculating a degree of certainty about malignancy (i.e. likelihood of malignancy), which degree represents a level of possibility of a pattern being a malignant pattern, with respect to a pattern embedded in the selected region (see column 33 lines 13-25.) Note that the system calculates the malignancy for the features including the ones in the arbitrary region. The calculation being made in accordance with an index value (i.e. ANN output) representing a feature of the pattern embedded in the selected region and in accordance with a correlation between the index value and possibility of a pattern being a malignant pattern (see column 33 lines 13-25), which correlation has been obtained from clinical results (see column 33 lines 13-25.) Note the correlation depends on the probability distribution of malignant and benign cases. The step of outputting at least the information for specifying the detected abnormal pattern candidate is a step of further outputting information representing

the degree of certainty about malignancy with respect to the pattern embedded in the selected region ( see column 36 lines 50-57.)

12. Re Claims 14-16, Claims 14-16 are rejected for the same reasons as claims 4-6 although they depend from different claims the additional limitations added by these claims are the same and therefore do no add any patentable weight to the already rejected claim 13.

13. Re claim 17 (see rejection for claim 13) Note in column 8 lines 9-34 and figure 2 Nishikawa discloses computer system configured to perform the above method, which is a means for accomplishing the method.

14. Re Claim 18-20, Claims 18-20 are rejected for the same reasons as Claims 4-6. Despite one set of claims being a method and one being a system the additional limitations added by these claims are the same. Therefore the prior art applied which teaches the method also teaches the corresponding systems.

### ***Rejections Under 35 U.S.C. 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claim 1-2 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takeo USPGPUB 2002/0062075 in view of Cothren et al. US 6,154,560.

16. Re claim 1, Takeo discloses an abnormal pattern candidate detection processing method, comprising the steps of: i) detecting an abnormal pattern candidate, which is embedded in a medical image, in accordance with a medical image signal representing a medical image, (see abstract) and ii) outputting at least information for specifying the detected abnormal pattern candidate (see abstract). Furthermore Takeo discloses an index value representing a feature of the abnormal pattern candidate, (see paragraph 22). Takeo does not disclose, wherein the method further comprises the step of calculating a degree of certainty about malignancy (i.e. likelihood of malignancy), which degree represents a level of possibility of a pattern being a malignant pattern, with respect to the abnormal pattern candidate, the calculation being made in accordance with an index value representing a feature of the abnormal pattern candidate and in accordance with a correlation between the index value and possibility of a pattern being a malignant pattern, which correlation has been obtained from clinical results, and the step of outputting at least the information for specifying the detected abnormal pattern candidate is a step of outputting information representing the degree of certainty about malignancy with respect to the abnormal pattern candidate together with the information for specifying the detected abnormal pattern candidate.

17. Cothren discloses the idea of correlating determined values (ie index) to a probability (i.e. certainty) of malignancy wherein the method further comprises the step of calculating a degree of certainty about malignancy, which degree represents a level of possibility of a pattern being a malignant pattern with respect to the abnormal pattern candidate (see column 20 lines 60-67 column 21 lines 1-5.) Note that Cothren uses a look up table to calculate percent probability of malignancy. The calculation being made in accordance with an index value representing a feature of the abnormal pattern candidate and in accordance with a correlation between the index value (i.e. determined value) and possibility of a pattern being a malignant pattern (see column 20 lines 60-67 column 21 lines 1-5.) Note that Cothren describes a correlation between a determined value and probability of malignancy. Which correlation has been obtained from clinical results (see column 20 lines 58-67.) Note the comparison is done with a distribution of empirical data. The step of outputting at least the information for specifying the detected abnormal pattern candidate is a step of outputting information representing the degree of certainty about malignancy with respect to the abnormal pattern candidate together with the information for specifying the detected abnormal pattern candidate (see column 20 lines 63-66.) One of ordinary skill in the art would readily recognize the advantage of having a probability of malignancy correlated to actual results because it is easier to interpret probability of malignancy then just a index value since the relative scale of the index value may not be known as described in therefore it would have been

obvious to one of ordinary skill in the art to combine the present inventions to reach the aforementioned advantage.

18. Re Claim 2 Takeo further discloses, wherein the index value is an index value utilized for the detection of the abnormal pattern candidate (see paragraph 22.) Note these "indices" are used for detection of the abnormal pattern candidate.
19. Re Claim 7, Takeo in view of Wang also recites means for accomplishing each method step of claim 1. The previous rejection of claim 1 shows all of this function. Takeo further discloses, "In the abnormal shadow detection processing, the digital image signal is analyzed by a computer, which is Takeo's means for accomplishing this method(see paragraph 6.)
20. Re claim 8, Claim 8 is rejected for the same reasons as claims 2. Despite one of claim being a method and one being a system the additional limitations added by the two claims are the same. Therefore the prior art applied which teaches the method also teaches the corresponding systems.
21. Claim 3, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishikawa in view of Wang US 6,266,435.

22. Re claim 3 Nishikawa discloses all of the steps of claim 1. Nishikawa does not disclose, the mark displayed at the location of the abnormal pattern candidate. However Wang discloses wherein the information for specifying the detected abnormal pattern candidate and the information representing the degree of certainty about malignancy with respect to the abnormal pattern candidate are a mark (see figure 2a and 2b and column 4 lines 23-27), which is displayed at a position for the indication of the abnormal pattern candidate on the medical image (see figure 2a and 2b), such that the kind of the mark may be altered in accordance with the degree of certainty about malignancy (see column 4 lines 23-27.) Wang further states with such an arrangement "a physician could efficiently allot his or her time in assessing/dismissing the markers" ( see column 8 lines 35-55.) Therefore one of ordinary skill in the art would have found it obvious to combine the afore mentioned features to reach the stated advantage.

23. Re claim 9, Claim 9 is rejected for the same reasons as claim 3. Despite one of claim being a method and one being a system the additional limitations added by the two claims are the same. Therefore the prior art applied which teaches the method also teaches the corresponding systems.

***Allowable Subject matter***

24. Claim 21 and 22 are allowable. Nishikawa discloses an abnormal pattern candidate detection processing method, comprising the steps of: i) detecting an

abnormal pattern candidate, which is embedded in a medical image, in accordance with a medical image signal representing a medical image, and ii) outputting at least information for specifying the detected abnormal pattern candidate, wherein the method further comprises the steps of: a) calculating a degree of certainty about malignancy, which degree represents a level of possibility of a pattern being a malignant pattern, with respect to a predetermined region in the medical image, which predetermined region has been set for each of pixels in the medical image, as the degree of certainty about malignancy corresponding to each of the pixels in the medical image, the calculation being made in accordance with an index value representing a feature of a pattern embedded in the predetermined region and in accordance with a correlation between the index value and possibility of a pattern being a malignant pattern, which correlation has been obtained from clinical results. (see rejection for claim 1.) Note the predetermined region is the entire image. Nishikawa does not disclose, forming a distribution image signal representing a distribution image, which represents a distribution of the degrees of certainty about malignancy in the medical image, in accordance with the thus calculated degrees of certainty about malignancy, each of which degrees corresponds to one of the pixels, and the step of outputting at least the information for specifying the detected abnormal pattern candidate is a step of further outputting the distribution image in accordance with the thus formed distribution image signal. Since this step is not taught by the prior art, claim 21 is allowable. Claim 22 is allowable because it depends from claim 21

25. Claim 23 would be allowable if all objections and rejections under U.S.C. 35 112 were overcome. Claim 23 is the means for performing claim 22 therefore also includes forming a distribution image signal representing a distribution image, which represents a distribution of the degrees of certainty about malignancy in the medical image, in accordance with the thus calculated degrees of certainty about malignancy, each of which degrees corresponds to one of the pixels, and the step of outputting at least the information for specifying the detected abnormal pattern candidate is a step of further outputting the distribution image in accordance with the thus formed distribution image signal. Therefore the computer of Nishikawa would not be configured to perform this function. Claim 24 includes allowable subject matter because it depends from claim 23.

### ***Conclusion***

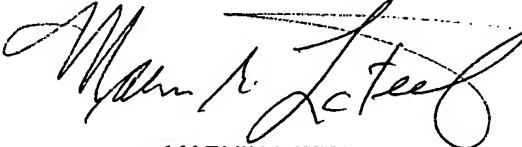
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Motsinger whose telephone number is 571-270-1237. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on 571-270-1245. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Motsinger  
12/15/2006

  
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SUPERVISORY PATENT EXAMINER